

**REMARKS*****Claim Status***

It is noted at page 2 of the Action that the requirement for election of species has been withdrawn, and that an Action on the merits has been made with respect to each of claims 1-14 and 17-20.

It is also noted with appreciation that the Examiner has stated at page 12 of the Action that claims 1-14 will be allowed if amended to overcome the rejections under 35 USC 112, second paragraph. As discussed further below, it is respectfully submitted that the above amendments overcome each of these 35 USC 112, second paragraph grounds for rejection, whereupon claims 1-14 should now be allowable.

The Examiner states at page 12 with respect to these claims that “the closest prior art, WO 00/55153, contains heterocyclic substituents correlating to Applicants R<sup>4</sup> moiety, which differs from the R<sup>4</sup> cycloalkyl substitutents as instantly claimed.” It is understood that the Examiner’s reference to the “closest prior art” is with respect to the eight compounds listed in Table VII of Example 13 and the single compound of Example 14 of WO 00/55153 wherein the carbonyl C-atom of the X group is bound to the central phenyl ring, as in the presently claimed compounds (see, e.g., Formula I). However, each of these nine compounds of Examples 13 and 14 contains a heterocyclic substituent at the position of Applicants’ R<sup>4</sup> moiety, i.e., a 3-fluoro-5-morpholinophenyl group, rather than the (3-6C)cycloalkyl R<sup>4</sup> moiety of Applicants’ present claims (optionally substituted with only non-cyclic substituents). In all other compounds named or exemplified in WO 00/55153 it is the amino N-atom of the X group that is bound to the central phenyl ring rather than the carbonyl C-atom of this group.

***Specification Amendments***

The specification has been amended to correct several inadvertent but obvious clerical errors. In each event, it is submitted that the existence of the error and its correction as made by the above amendments would have been readily apparent to the skilled person reading the specification and that, therefore, no new matter is added by these specification amendments. Specifically:

- At specification page 6, line 10, the inadvertent recitation of “cyclopentenyl” has been deleted. It would be readily apparent to the skilled person that cyclopentenyl is *not* a (3-6C)cycloalkyl.
- In Table 11 at specification page 114, the heading of the left column has been corrected from “R” to read “R-O-.” Since each of the listed substituents under this heading includes the “oxy” component of “R-O-,” it would be readily apparent to the skilled person that the listed substituents represent “R-O-” rather than just the “R” component of this substituent as shown in the structural diagram above the Table.
- Similarly, in Table 12 at specification page 118, the heading of the left column has been corrected from “R” to read “R-O-.” Since each of the listed substituents under this heading includes the “oxy” component of “R-O-,” it would be readily apparent to the skilled person that the listed substituents represent “R-O-” rather than just the “R” component of this substituent as shown in the structural diagram above the Table.
- In Table 13 at pages 121-122, the “ethoxy” component at the end of the last 10 named substituents in the left column has been removed. This is consistent with the first 6 named substituents in this column, and the need for and nature of this amendment would be readily apparent to the skilled person in that this column is headed just “R” and the “ethoxy” component of these substituents is already included in the structural diagram above this Table.

#### ***Claim Amendments***

Claim 1 has been amended to insert a definition of “heteroaryl” as recited in any R<sup>1</sup> substituent, which definition is taken from specification page 6, lines 23 to 26, and claim 1 has also been amended to insert a definition of “heterocycl” as recited in any R<sup>1</sup> substituent, which definition is taken from specification page 7, lines 8 to 11. The definitions carry over to (and are necessarily incorporated into) each of claims 2-14 without having to be repeated therein because of the dependency of each of these claims on claim 1.

Claim 1 has also been amended to remove the inadvertent inclusion of “aryl” in the statement “and wherein any aryl, heteroaryl or heterocycl group in a R<sup>1</sup> substituent may...” in the 6<sup>th</sup> line from the bottom of page 6 above. This error and the need for deleting “aryl” would be

readily apparent to the skilled person reading this claim since the preceding definition of R<sup>1</sup> does not include "aryl."

Claim 14 has been amended to more clearly state the readily apparent intent that the functional groups that are optionally protected are any functional group in the variable groups that are being referred to in that passage. Moreover, it would be readily apparent to the skilled person that the intent could not be to protect the functional groups that are involved in the particular reactions recited in these process-for-making claims.

Method of treatment claims 17-20 have been newly cancelled (claims 15-16 and 21-23 having previously been cancelled) in order to expedite this application to allowance, in view of the Examiner's above-noted statement with respect to the potential allowability of compound and process-for-making claims 1-14.

New claims 24 to 28 have been added by the above amendments, each directed toward a single compound of an Example as noted below, or a pharmaceutically-acceptable salt thereof as disclosed in the specification at page 36, line 11, referring to salts of the compounds listed from specification page 27, line 10 to page 36, line 10, which listing includes these compounds as also noted below:

- New claim 24 is directed toward the compound *N*-cyclopropyl-4-methyl-3-[6-(4-methylpiperazin-1-yl)-4-oxoquinazolin-3(4H)-yl]benzamide or a pharmaceutically acceptable salt thereof, having specification support in Example 5 and in the compound listing at page 27, line 11.
- New claim 25 is directed toward the compound *N*-cyclobutyl-4-methyl-3-[6-(4-methylpiperazin-1-yl)-4-oxoquinazolin-3(4H)-yl]benzamide or a pharmaceutically acceptable salt thereof, having specification support in Example 6 and in the compound listing at page 27, line 12.
- New claim 26 is directed toward the compound *N*-cyclopropyl-4-methyl-3-[4-oxo-6-(4-propylpiperazin-1-yl)quinazolin-3(4H)-yl]benzamide or a pharmaceutically acceptable salt thereof, having specification support in Example 9 and in the compound listing at page 27, line 29.
- New claim 27 is directed toward the compound *N*-cyclopropyl-4-methyl-3-[6-(4-isopropylpiperazin-1-yl)-4-oxoquinazolin-3(4H)-yl]benzamide or a pharmaceutically

acceptable salt thereof, having specification support in Example 10 and in the compound listing at page 27, lines 21-22.

- New claim 28 is directed toward the compound *N*-cyclopropyl-4-methyl-3-[7-(4-methylpiperazin-1-yl)-4-oxoquinazolin-3(4*H*)-yl]benzamide or a pharmaceutically acceptable salt thereof, having specification support in Example 11 and in the compound listing at page 30, line 5.

It should be clear from the above that no new matter has been added, and entry of these amendments is therefore believed to be appropriate and is respectfully requested. These amendments are being made without disclaimer or prejudice to Applicants' right to prosecute any cancelled subject matter in one or more continuing applications.

Following entry of these amendments, claims 1-14 and 24-28 remain pending in this application.

***Claim Rejections - 35 USC § 112, second paragraph***

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the Examiner asserts that claim 1 and those claims dependent thereon are rejected because the claims define variables (where applicable) as heteroaryl, heterocyclyl, heteroaryl-alkoxy, heteroaryloxy, heterocyclyoxy, heterocyclamino. These terms are said to be indefinite since the specification does not define the ring size, heteroatom, number and nature of substituents, and the exact point of contact with the atom(s) for the substituents.

Applicants respectfully disagree with the Examiner's assertion in that it is believed that ample guidance as to the meaning of these terms is given in the specification at page 6, line 23 through page 7, line 23. Nevertheless, claim 1 has been amended to more specifically define *in the claims* the terms heteroaryl and heterocyclyl as used in the R<sup>1</sup> substituents. It is respectfully submitted that with the guidance provided by the lists of specific suitable values for such heteroaryl and heterocyclyl groups, combined with the skill and knowledge in the art, these terms would not be considered indefinite by persons skilled in this art.

Claim 14 is also rejected as being indefinite for reciting "any functional group is optionally protected". The Examiner queries whether the functional group referred to is the hydroxyl group, the ketone group, the carboxyl group?

It is believed that the intent of these passages in process-for-making claim 14 would already be apparent to the skilled person. Thus, from the context of the passage stating "wherein variable groups are as defined in claim 1 and wherein any functional group is optionally protected," it is believed apparent that the intent is to refer to any functional group in these *variable groups*, *i.e.*, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup>. Nevertheless, in an effort to expedite the allowance of this application, claim 14 has been amended with respect to both recitations of "any functional group" to specifically recite "any functional group in these variable groups is optionally protected."

Therefore, in view of the above amendments to claims 1 and 14 and the foregoing remarks, it is believed that all grounds for this section 112, second paragraph, rejection have been overcome. It is therefore respectfully requested that this rejection be withdrawn, placing claims 1-14 in condition for allowance.

***Claim Rejections - 35 USC § 112, first paragraph***

The rejection of claims 17-19 under 35 U.S.C. 112, first paragraph as not being enabled has been obviated by the cancellation of these claims. The cancellation of these claims has been made for purposes of expediting the allowance of this application, and Applicants reserve the right to prosecute the subject matter of these claims in one or more continuing applications.

***Conclusion***

It is respectfully submitted that this application is now in condition for allowance by reason of the above amendments and the foregoing remarks. The section 112, 2<sup>nd</sup> paragraph grounds for rejection of claims 1-14 are believed to have been overcome by the above amendments to claims 1 and 14 and the comments thereon. The rejection of method of treatment claims 17-19 has been obviated by the cancellation of these claims. New claims 24-28 are directed toward specific compounds within the scope of claim 1 *et seq.* and were already listed within claim 13, and therefore should be allowable along with claims 1-14.

Therefore, inasmuch as all of remaining claims 1-14 are now in condition for allowance, a notice to that effect is believed to be in order and is respectfully requested.

***Table of Related Applications***

The Examiner's attention is directed to the following updated table co-pending U.S. patent applications and patents of Applicants' assignee, which might be considered technically related to the present application:

Inventor	U.S. Serial No. Filing Date	U.S. Pub. No. Pub. Date	PCT Pub. No. PCT Pub. Date	Status
Brown et al.	09/936,698 09/17/2001	6,548,514 04/15/2003	WO 00/55120 09/21/2000	Patented
Brown et al.	10/353,127 01/29/2003	6,794,380 09/21/2004	WO 00/55120 09/21/2000	Patented
Brown et al.	09/674,428 01/01/2000	6,465,455 10/15/2005	WO 99/59960 11/25/1999	Patented
Brown et al.	09/674,560 11/02/2000	6,579,872 06/17/2003	WO 99/59959 11/25/1999	Patented
Brown et al.	10/424,127 04/28/2003	6,956,037 10/18/2005	WO 99/59959 11/25/1999	Patented
Brown et al.	09/508,055 03/07/2000	6,498,274 12/24/2002	WO 99/15164 04/01/1999	Patented
Brown et al.	10/265,736 10/08/2002	6,686,467 02/03/2004	WO 99/15164 04/01/1999	Patented
Brown	09/936,758 11/15/2001	7,008,945 03/07/2006	WO 00/55153 09/21/2000	Patented
Brown	11/176,327 07/08/2005	7,442,704 10/28/2008	WO 00/55153 09/21/2000	Patented
Brown	11/505,904 08/18/2006	7,332,483 02/19/2008	WO 00/55153 09/21/2000	Patented
Cumming	09/937,018 09/20/2001	6,784,174 08/31/2004	WO 00/56738 09/28/2000	Patented
Brown et al.	09/762,106 02/02/2001	6,821,965 11/23/2004	WO 00/07980 02/17/2000	Patented
Brown et al.	10/947,463 09/23/2004	US 2005-0038081 02/17/2005	WO 00/07980 02/17/2000	Assigned to Examiner Timothy E. Betton in GAU 1617; Notice of Allowance mailed October 29, 2009.
Brown et al.	09/762,107 02/02/2001	6,432,949 08/13/2002	WO 00/07991 02/17/2000	Patented
Brown et al.	10/192,495 07/11/2002	7,060,700 06/03/2006	WO 00/07991 02/17/2000	Patented
Brown et al.	11/125,321 05/10/2005		WO 00/07991 02/17/2000	Abandoned
Brown et al.	09/787,882 03/23/2001	6,455,520 09/24/2002	WO 00/18738 04/06/2000	Patented
Cumming	09/787,883 03/23/2001	6,593,333 07/15/2003	WO 00/20402 04/13/2000	Patented

Inventor	U.S. Serial No. Filing Date	U.S. Pub. No. Pub. Date	PCT Pub. No. PCT Pub. Date	Status
Cumming	10/441,084 05/20/2003	6,716,847 04/06/2004	WO 00/20402 04/13/2000	Patented
Cumming	10/070,360 03/05/2002	6,846,827 01/25/2005	WO 01/27089 04/19/2001	Patented
Brown	10/581,305 10/12/2006	<b>US 2007-0135440</b> 06/14/2007	<b>WO 2005/061465</b> 07/07/2005	Assigned to Exmr. Laura Lynne Stockton in GAU 1626; Response to Restriction Requirement & Preliminary Amendment filed November 2, 2009
Nash	11/793,781 06/20/2007	<b>US 2008-0146566</b> 06/19/2008	<b>WO 2006/067444</b> 06/29/2006	Assigned to Exmr. Zinna Davis in GAU 1625; Restriction Requirement mailed October 20, 2009
Nash	11/817,137 06/06/2008	<b>US 2009 0124604</b> 05/14/2009	<b>WO 2006/090143</b> 08/31/2006	Assigned to Exmr. Brian McDowell in GAU 1624; Response to Restriction Requirement & Preliminary Amendment filed September 22, 2009
Brown	12/063,631 02/12/2008	—	<b>WO 2007/020411</b> 02/22/2007	Undergoing Preeexam Processing

The documents cited in **bold** on the above table are listed on the form PTO-1449 accompanying the further Information Disclosure Statement submitted herewith, and a copy of each **bold** published PCT application is being submitted therewith. All other documents listed in the above table have been formally cited in a previously submitted Information Disclosure Statement and a copy of each such document (with the exception of the US published applications and US patents), has been submitted with a previously filed Information Disclosure Statement.

It is assumed that the Examiner has ready electronic access to the listed US pending applications, but the undersigned will provide a copy of any document from those files if requested by the Examiner.

**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. §1.136(a)(3).

Respectfully Submitted,  
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